

510(k) Summary**As Required by 21 section 807.92 (c)**

K020749

- 1-Submitter Name:** Everyway Medical Instruments Co., Ltd
- 2-Address:** 3FL., No. 5, Lane 155, Sec. 3, PeiShen Rd., Shen Keng
Hsiang
Taipei Hsien
Taiwan, R.O.C.
- 3-Phone:** 886-2-2662-0038
- 4-Fax:** 886-2664-5566
- 5-Contact Person:** Mr Robert Tu (General Manager)
- 6-Date summary prepared:** February 27th, 2002
- 7- Official Correspondent:** Mansour Consulting
- 8- Address:** 1308 Morningside Park Dr
Alpharetta, GA 30022 USA
- 9- Phone:** (678) 908-8180
- 10- Fax:** (425) 795-9341
- 11- Contact person:** Jay Mansour, president
- 12-Device Trade or Proprietary Name:** EV-803 Digital TENS
- 13-Device Common or usual name:** Stimulator, Nerve, Transcutaneous, for pain relief
- 14-Device Classification Name:** Stimulator, Nerve, Transcutaneous, for pain relief
- 15-Substantial Equivalency** is claimed against the following device:
TransAmerica Medical Systems, 510k #k010782 (refer to Appendix 2 for FDA website printout)
This notification for EV-803 is of the ABBREVIATED type as per the declaration of conformity included in this summary
- 16-Description of the Device:** EV-803 Digital Tens is a battery operated pulse generator that sends electrical impulses through electrodes to the body and reach the nerves causing pain. The device is provided with two controllable output channels, each independent of each other. An electrode pair can be connected to each output channel. The electronics of the EVERYWAY EV-803 DIGITAL TENS create electrical impulses whose intensity, duration, number per second and modulation may be altered with the controls/switches. Press buttons are very easy to use and the large liquid crystal display showing the exact mode and values of parameters are very convenient for patients.
- 17-Intended use of the device:** *(Indications for use typed on a separate FDA form)*
EV-803 Digital TENS is an electrical nerve stimulator intended for use for pain relief by applying an electrical current to electrodes on a patient's skin to treat pain
- 18-Safety and effectiveness of the device:**
This device is safe and effective as the predicate device *Transamerica Digital EMS*. Indeed, it is identical. The same device which was cleared by 510k #k010782 for the distributor TransAmerica Medical Systems is submitted here for the original manufacturer in Taiwan EVERYWAY MEDICAL INSTRUMENTS CO., LTD.
Refer to the tabulated comparison (Paragraph 19 below)
- 19-Summary comparing technological characteristics with other predicate device:**

FDA file reference number	510k #k010782
Attachments inside notification submission file	510k summary print out
TECHNOLOGICAL CHARACTERISTICS	<i>Comparison result</i>
Indications for use	Identical
Target population	Identical
Design	Identical
Materials	Identical
Performance	Identical
Sterility	Identical
Biocompatibility	Identical
Mechanical safety	Identical
Chemical safety	Identical
Anatomical sites	Identical
Human factors	Identical
Energy used and/or delivered	Identical
Compatibility with environment and other devices	Identical
Where used	Identical
Standards met	Identical
Electrical safety	Identical
Thermal safety	Identical
Radiation safety	Identical



EVERYWAY MEDICAL INSTRUMENTS CO., LTD.


3FL., No.5, Lane 155, Sec. 3, PeiShen Rd., Shen Keng Hsiang, Taipei Hsien, Taiwan, R.O.C.
Tel: 886-2-2662-0038 Fax: 886-2-2664-5566 E-mail: everywy@ms2.hinet.net

DECLARATION OF CONFORMITY

This is to declare and confirm that **Everyway Medical Instruments Co., Ltd.** conforms in its manufacturing of Transcutaneous Electrical Nerve Stimulators EV-803 Digital TENS to the following recognized standards:

Standards met and standards tested against

Standards met and standards tested against	
Supervision of product and design: QSR (FDA's Quality System Requirements) DIN EN ISO 9002/08.1994 DIN EN 46002/09.1996 EE Directive 93/42 (CE Mark) ISO 13488/12.1996	Inapplicable requirements or deviations
	Identification of any way(s) in which the standard was adapted for the application of the device, i.e., identification of an alternative series of tests that were performed
	Specification of any deviations from each applicable standard
	Specification of the differences that may exist between the tested device and the device to be marketed and justification of the test results
Technical standards: EN 60601-1:1990+A1:1993+A2:1995 EN60601-1-2:1993	For QSR: Not applicable
	For ISO 9002: 1994, EN 46002, ISO 13488 and CE Mark:
	TUV Rheinland Product Safety GmbH- Am Grauen Stein –D-51105 Köln.
	TUV Rheinland Product Safety GmbH- Am Grauen Stein –D-51105 Köln.

Name, Signature and position	Robert Tu/ General Manager 
Date	02/27/2002



OCT 31 2002

Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

Mr. Jay Mansour
Representing Everyway Medical Instruments Co., Ltd.
Mansour Consulting, L.L.C.
1308 Morningside Park Drive
Alpharetta, Georgia 30022

Re: K020749
Trade/Device Name: EV-803 Digital TENS
Regulation Number: 21 CFR 882.5890
Regulation Name: TENS Device for Pain Relief
Regulatory Class: Class II
Product Code: GZJ
Dated: July 26, 2002
Received: August 1, 2002

Dear Mr. Mansour:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

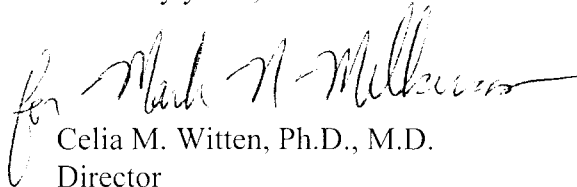
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice

requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for *in vitro* diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "for Mark H. Miller", is written over the typed name "Celia M. Witten, Ph.D., M.D.". The signature is fluid and cursive.

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K020749

DEVICE NAME: Digital Transcutaneous Electrical Nerve Stimulator (EV-803 Digital TENS)

INDICATIONS FOR USE:

EV-803 Digital TENS is an electrical nerve stimulator indicated for use for pain relief by applying an electrical current to electrodes on a patient's skin to treat pain.

In particular, this device is indicated for use for:

- Symptomatic relief and management of chronic (long term) intractable pain
- Adjunctive treatment in the management of post surgical and post traumatic acute pain problems.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use _____
(Optional Format 1-2-9)

for Mark N. Miller
(Division Sign-Off)
Division of General Restorative
and Neurological Devices

510(k) Number K020749

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